

#### REMARKS

Reconsideration in view of the foregoing amendments and following remarks is respectfully requested.

Following is a discussion of each of the items from the Office action mailed March 29, 2004.

Claims 1-7, 9-15, 17-23, 25, 32 and 33 have been amended. Claims 34-36 have been added. Claims 8, 16 and 24 have been canceled. The formal drawings have been submitted. A substitute specification has been provided. The changes to the specification are purely editorial and have been made to correct misspellings, to eliminate grammatical informalities, to correct previously erroneous reference numerals, and to clarify the description, as well as to provide consistency in the terminology used so as to ensure that the words and phrases used in the claims find clear antecedent basis in the specification, as required by 37 CFR 1.75(d). No new matter has been added.

#### **Election/Restriction**

Examiner's statements regarding election/restriction are acknowledged. Applicants will prosecute claims to the species of FIG. 5 until an allowable generic claim provides for additional species. The present amendment should further clarify the various embodiments and descriptive figures. As will be discussed below, the specification discloses a system for inflation and deflation ("evacuation") of an occlusion balloon on a guidewire. Key components include inflation/evacuation means, and sealing means. Applicants envision the most useful embodiments to include both as a handheld apparatus connectible to a guidewire assembly such as shown at 22. Whether the handheld apparatus includes one, two, three, or more individual components is of lesser importance, provided that the functions of inflation, evacuation, and

sealing are provided in apparatus which is connectible to a guidewire assembly.

The informal drawings originally submitted have apparently caused some confusion. Formal drawings to clarify the disclosure are provided. In particular, FIG. 5 has caused some confusion because of certain elements which are difficult to visualize in that view, or were not properly labeled. Sealing system 60a is shown in FIG. 5 but was not labeled or described as such. Instead, structure 102 shown in FIG. 5 was said to include crimping mechanism 66 (sic, 66a) and sealing mechanism 68 (sic, 68a). Actually, it is the sealing system 60a rather than the structure 102 which includes 66a and 68a, and 60a is supported by structure 102. First aperture 62 is present but is hidden from view in FIG. 5. The first aperture 62 is a component of sealing system 60a and its inclusion would have been clear if "sealing system 60a" had been used in FIG. 5 and the description thereof rather than "structure 102". First aperture 62 must be and in fact is present since that is how the device is connected to the guidewire assembly for use, as described at various locations in the specification. The device of FIG. 5 has sealing system 60a attached to gas inflation/evacuation system 80a, and a fluid passageway connects sealing system 60a to gas inflation/evacuation system 80a. This passageway is internal and hidden from view in FIG. 5, but it is clearly present since the guidewire assembly connects to sealing system 60a and is inflated and evacuated by gas inflation/evacuation system 80a and therefore must be fluidly connected via a fluid passage. Thus, certain of the withdrawn claims in fact do read on FIG. 5: namely, claims 2, 3, 10-12, 17 and 18. Examiner's objection to claim 10 is based on an erroneous interpretation of the claim. Claim 10 includes a sealing system that is removably connectible to the guidewire assembly 22. Claim 10 is stating that the

sealing assembly and the guidewire assembly can be connected and disconnected from each other, not that the sealing assembly can be connected and disconnected from the syringes. Claims 10 and 12 are presently amended to better define over the prior art. Applicants assert that the amended claim 10 reads on FIG. 5, and request reconsideration of claim 10 and dependent claims 11, 12 and 17. Likewise, claims 3 and 18 now clearly read on FIG. 5.

### 35 U.S.C. 102 Rejection of Claim 1

Examiner rejects claim 1 as anticipated by Valley USP 6,251,093. Examiner is incorrect regarding certain characterizations of the Valley device. Nevertheless, Examiner is correct in that claim 1 would be improved by adding further structural language so that it clearly does not read on the Valley device. There are real, physical differences which make the present invention novel over Valley. For the record, Examiner's characterization of the Valley device as a gas inflation/deflation system at col. 16, 5-15 is incorrect. Valley clearly intends the device to be used with a liquid--that is why it must be dimensioned with such a large inner diameter (col. 15, 57-63) and she explicitly states a preference for saline solution or saline/contrast mixture (col. 15, 60-67+). Examiner correctly points out that, even though Valley does not anticipate her device being used with gas as the working fluid for inflating the occlusion balloon to occlude a vessel, the Valley device could conceivably be used with gas; therefore, additional structural language has been added to claim 1 to further distinguish from Valley. Examiner characterizes the Valley device as being connectible to a proximal portion of a guidewire assembly and introducing biocompatible gas into the guidewire assembly; Examiner is incorrect--the Valley device has a catheter with a balloon, Valley does not anticipate use with

a guidewire having an occlusive balloon. There are structural differences required to accommodate a guidewire rather than a catheter; those differences of the present invention have been included in the amended claim 1. Examiner cited introducing a biocompatible gas (Valley col. 13, 45-50) but this is only a partial inflation with gas to aid in advancing the pulmonary venting catheter through the vasculature (col. 13, 45-47); in use, occlusion balloon 60 is inflated with a liquid (col. 15, 65-66). Examiner further refers to a guidewire assembly' (897, figure 34); characterization of item 897 as a guidewire is incorrect. Rather, item 897 is a shaft of a catheter 895 having a diameter of 3-4 mm (col. 40, 6-13). Again, the Valley device is for a catheter, whereas the present device is for a guidewire. Nevertheless, additional structural language has been added to claim 1 to further distinguish from Valley. Examiner cites means for selectively sealing the proximal portion of the guidewire assembly... at col. 38, 12-19; this is an incorrect characterization. The citation instead refers to a portion of a tubular cannula body 851 which can be temporarily occluded by a clamp; this makes no sense if the lumen to be temporarily occluded is a lumen in a guidewire, since guidewires are generally not resilient tubular structures--the Valley mechanism would provide a permanent sealing of a tubular guidewire, but Valley did not anticipate use of the device with an occlusion guidewire anyway. Further, the clamp used by Valley provides blockage against passage of blood through a lumen, and is not used to seal a balloon inflation lumen to maintain balloon occlusion while the device is used as a guidewire. Again, the added structural language to claim 1 further distinguishes from Valley.

### **35 U.S.C. 102 Rejection of Claim 2**

Examiner rejects claim 2 as anticipated by Valley USP 6,251,093. Examiner states that Valley has a pump that adds/removes air. Valley discloses a syringe or a mechanical inflation device to inflate the occlusion balloon with saline or saline/contrast medium--liquids. Nevertheless, a syringe can sometimes be used to pump a gas. The added structural language in claim 1 now distinguishes the present invention as claimed from that of Valley, and the additional limitation of claim 2 is not required to distinguish from Valley.

### **35 U.S.C. 102 Rejection of Claim 4**

Examiner rejects claim 4 as anticipated by Valley USP 6,251,093. Examiner states that Valley has a means for sealing that comprises a crimping mechanism. This is incorrect. First, Valley uses a clamp to reversibly clamp a resilient tube--the clamping of Valley does not result in a permanent deformation or crimp of the tube. Also, Valley has no mechanism enabling the re-opening of the tube. In contrast, claim 4 cites a crimping mechanism for the present invention; the crimping mechanisms shown in the figures produce a permanent deformation of a tubular metallic guidewire. In addition, the present invention enables re-opening of the permanently deformed tube; note, for example, at page 14, lines 25-27, page 15, lines 1-7, and elsewhere.

### **35 U.S.C. 103 Rejection of Claims 8 and 9**

Examiner rejects claim 8 and 9 as obvious in view of Valley USP 6,251,093. Examiner is quite correct that packaging a medical device in a sterile packaging containing biocompatible gas is common. Therefore, Applicants cancel claim 8 with the present amendment. What is different with the present invention is that a syringe such as the inflation syringe of FIG. 5 is

preferably filled with a gas which can safely be used in a blood vessel. Air could be used, but it would have significant risk of injury since any air which might leak out of the occlusive balloon, or at any point along the guidewire assembly, could create an air embolus in the vessel, with unfavorable sequelae. Preferably, a gas such as carbon dioxide, nitrous oxide, or other gases which are known in the art to be safer if injected into a blood vessel by mistake, would be used. One approach to packaging the present invention includes filling the syringe(s) and the interior of the package with a safely-injectable gas such as carbon dioxide. Thus, the present invention is at least unusual, and possibly unique, in advantageously being packaged in a biocompatible gas other than air. Claim 9 has been amended to further clarify this matter, and to define over the prior art. Nevertheless, claim 1, from which claim 9 now depends, should now be allowable upon the present amendment, and the additional limitation of claim 9 is not required to distinguish from Valley.

#### **Claims Now Entitled to Examination**

In view of the amendments made to claims 1, 2, 4 and 9, and the arguments presented with respect to these claims, it is submitted that these claims 1, 2, 4 and 9 are clearly patentable over the prior art. Accordingly, these claims 1, 2, 4 and 9 are allowable, and reconsideration and allowance thereof is respectfully requested.

The elected species is **FIG. 5**, and by the present amendment claims 3, 10-12, 17 and 18 now read on **FIG. 5** in addition to claims 2 and 4. Also, the new claims 34-36 read on **FIG. 5** (claims 34 and 35 are generic, and claim 36 is specific to the **FIG. 5** species). Accordingly, claims 34 and 35, being generic, are entitled to examination with claim 1, and claims 3, 10-12, 17, 18 and 36, being directed to the species of **FIG. 5**, are

entitled to examination whether or not there is an allowable generic claim. However, claim 1 is deemed to be allowable and it is generic to all species disclosed in the application. Consequently, all pending claims in this application are entitled to examination because they either depend on allowable generic claim 1 or they include all of the limitations of allowable generic claim 1. In this latter respect, it should be noted that independent claims 10, 18, 22 and 32 contain all of the limitations of claim 1 defined in terms more specific than the broader manner in which they are defined in claim 1.

Thus, this amendment not only renders claims 1, 2, 4 and 9 clearly allowable, but also renders dependent generic claims 34 and 35 and claims 3, 10-12, 17, 18 and 36 readable on the elected species of FIG. 5 allowable. Moreover, even claims 5-7, 13-15, 19-23, 25, 32 and 33 are allowable because they include all of the limitations of a generic claim.

Reconsideration and allowance of all pending claims is, therefore, respectfully requested.

If there are any further issues yet to be resolved to advance the prosecution of this patent application to issue, the Examiner is requested to telephone the undersigned counsel.

